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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,793	04/14/2004	James J. Modliszewski	60310-USA	6666

7590 03/06/2006

Paul A. Fair - Patent Administration
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,793

Applicant(s)

MODLISZEWSKI ET AL.

Examiner

Everett White

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/26/04 & 9/23/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed Jul. 26, 2004, Aug. 15, 2005, and Nov. 14, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 44 and 45 of copending Application No. 10/824,688. Both applications disclose a delivery system comprising a homogenous, thermoreversible gel film, wherein said gel film comprises: (i) a film forming amount of a carrageenan and optionally at least one of a plasticizer, a

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second film former, a bulking agent, and a PH controlling agent; and (ii) an active substance; wherein the active substance is at least one member selected from the group consisting of an oral care agent, a breath freshening agent, an antimicrobial agent, a cooling agent, a pharmaceutical agent, a nutraceutical agent, a salivary stimulant agent, a vitamin, a mineral, a coloring agent, cosmetic ingredient, agricultural active, a sweetener, a flavorant, a fragrance and a food.

The instantly claimed delivery system differs from the delivery system of the 10/824,793 application by claiming the use of a low molecular weight carrageenan having a viscosity of 5 to less than 10 cP at 75°C.

The delivery system of the instant claims differs from the delivery system of the 10/824,688 application by claiming that the gel film thereof comprises .kappa.-2 carrageenan as opposed to a the broadly claimed carrageenan of the 10/824,688 application.

However, the 10/824,688 application does broadly include .kappa.-2 carrageenan.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to replace the carrageenan in the delivery system of the 10/824,688 application with kappa-2 carrageenan in view of their closely related structures and the resulting expectation of similar film and gelling properties.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-17, 20, 21 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376).

Applicants claim a delivery system comprising a homogenous, thermoreversible gel film, wherein said gel film comprises: (i) a film forming amount of kappa-2 carrageenan and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent; and (ii) an active substance. Additional limitations in the dependent claims include the delivery system wherein said active substance is at least one of an oral care agent, a breath freshening agent, antimicrobial agent, cooling agent, a pharmaceutical agent, a nutraceutical agent, a salivary stimulant agent, cosmetic ingredient, agricultural active, a vitamin, a mineral, a coloring agent, a sweetener, a flavorant, a fragrance or a food; the delivery system wherein said gel film further comprises at least one of potassium, sodium or ammonium cation in an amount less than 20% by dry weight of the kappa-2 carrageenan in the gel film; the delivery system wherein said kappa-2 carrageenan is present in an amount of at least 0.5% by dry weight of the gel film; the delivery system wherein said kappa-2 carrageenan is present in an amount of at least 10% to at least 80% of the total dry weight of film formers in the gel film; the delivery system wherein said kappa-2 carrageenan is the

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only film former present in the gel film; the delivery system wherein said second film former is selected from the group consisting of starch, starch derivative, starch hydrozylate, cellulose gums, kappa carrageenan, iota carrageenan, alginates, propylene glycol alginate, polymannan gums, dextran, pullulan, gellan, pectin, alkylcellulose ethers and modified alkyl cellulose ethers; the delivery system wherein said plasticizer is at least one member selected from the group consisting of glycerin, sorbitol, maltitol, lactitol, corn starch, fructose, sucrose, and polyalkylene glycols; the delivery system wherein said bulking agent is at least one member selected from the group consisting of microcrystalline cellulose, sugar, corn syrurp, polydextrose, starch, starch derivatives, inulin, and starch hydrozylates; the delivery system having a break force strength of at least 2,500 grams to at least 6,000 grams.

The Gennadios patent discloses a gelatin-free capsule for use in oral administration of medicines, cosmetic or bath applications, or dietary supplements which can be prepared from compositions comprising (a) 8-50% by weight of water-dispersible or water-soluble plasticizer, (b) 0.5 to 12% by weight .kappa.-carrageenan, (c) 0 to 60% dextrans, and (d) 1% to 95% by weight water, with the .kappa.-carrageenan comprising at least 50% by weight of all gums forming or contributing to formation of thermoreversible gels in the composition (see abstract). The Gennadios patent discloses that a capsule for oral administration or cosmetic application may comprise a fill material to be administered to a patient or subject and wherein the capsule comprises an aqueous based film comprising (a) water-dispersible or water-soluble plasticizer, and (b) carrageenan, with the carrageenan comprising at least 50% or 75% by weight of .kappa.-carrageenan, and the carrageenan comprising at least 50% or 75% by weight of all gums which form or contribute to the formation of thermoreversible gels (see abstract). This description of the gelatin-free capsule of the Genndios patent embraces the subject matter of instant Claims 1, 2 and 4-10. See column 2, lines 3 and 4 wherein the Gennadios patent discloses that Kappa Carrageenan is known to form gels in the presence of potassium cations, which embraces the subject matter of instant Claim 3. See column 3, lines 44-54, wherein the Gennadios patent discloses that carbohydrates such as glycerin, alkylene glycols, sorbitol, maltitol, lactitol, xylitol, corn syrup solids, and

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other polyols or combinations thereof can be used as plasticizers, which is identical to the plasticizers disclosed in instant Claim 13. See column 4, 2nd paragraph wherein the Gennadios patent discloses that mannan gums (e.g., locust bean gum, konjac gum, and tara gum) which have a synergistic gelling effect with .kappa.-carrageenan can be added to increase gel strength and elasticity. In this paragraph, Gennadios also discloses that part of the .kappa.-carrageenan may be substituted by iota-carrageenan (up to a maximum of 50% or 25% by weight of the .kappa.-carrageenan) which forms "softer" and more elastic gels. This description of the combination of .kappa.-carrageenan with other mannan gums and iota-carrageenan embraces the use of a second film former disclosed in instant Claims 12 and 13. The Gennadios patent further discloses that hydrolyzed starches, such as maltodextrin are added to (1) increase solids concentration in the gel mass (2) aid heat sealing by increasing wet film tackiness, and (3) prevent "hazing" of dried carrageenan capsules induced by the gelling salt and, if added, the mannan gums, wherein maltodextrin from corn starch is optionally used due to wide availability and low cost. The material added by Gennadios to increase solids concentration in the gel mass meet the requirement of using bulking agents in instant Claim 13. The break force strength of the delivery system set forth in instant Claims 14-17 are noted, but are not considered unobvious over the delivery system disclosed in the Gennadios patent since products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01

The delivery system of the instant claims differs from the delivery system (capsule) of the Gennadios patent by claiming that the gel film thereof comprises .kappa.-2 carrageenan as opposed to .kappa.-carrageenan used in the Gennadios patent.

However, the substitution of .kappa.-carrageenan with kappa-2 carrageenan is obvious since both compounds are classified as kappa-carrageenan and minor differences in the stability of gel strength between kappa-2 carrageenan and a similar

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amount of kappa-carrageenan/iota-carrageenan combination does not show unexpected results. Where the claimed and prior art compounds possess a close structural relationship and a specific significant property in common which renders the claimed compounds obvious to one skilled in the art, they are effectively placed in the public domain and unpatentable per se, even though the Applicant has discovered that they possess an additional activity. In re Mod et al. (CCPA 1969) 408 F2d 1055, 161 USPQ 281 ; Monsanto Co. v. Rohm & Haas Co. (DC Pen 1970) 420 Fsupp 950, 164 USPQ 556 (affd. On other grounds, 172 USPQ 323).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to replace the kappa-carrageenan in the delivery system of the Gennadios patent with kappa-2 carrageenan in view of their closely related structures and the resulting expectation of similar film and gelling properties.

6. Claims 18, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376).

Applicants claim a process for preparing the homogeneous gel film delivery system comprising the steps of: (i) heating, hydrating, mixing, solubilizing and, optionally, de-aerating said kappa-2 carrageenan and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous molten composition, wherein said temperature is at or above the solubilizing temperature of said composition; (ii) adding an effective amount of an active substance either prior to or after formation of the molten composition; and (iii) cooling said molten composition containing said active substance at or below its gelling temperature to form said gel films containing said active substance. Additional limitations in the dependent claims include the process wherein said active substance is at least one of an oral care agent, a breath freshening agent, an antimicrobial agent, a cooling agent, a pharmaceutical agent, a nutraceutical agent, a salivary stimulant agent, a vitamin, a mineral, a cosmetic ingredient, an agricultural active, a coloring agent, a sweetener, a flavorant, a fragrance, and a food; the delivery system having a break

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sweetener, a flavorant, a fragrance, and a food; the process wherein said apparatus is a Ross mixer, Stephan processor, extruder, jet cooker or fluid mixing apparatus.

The Gennadios patent discloses a process for forming the capsules (the delivery system) comprising heating the composition, casting or extruding the composition into a film, gelling the composition by cooling, associating a fill material with the gelled composition (usually as a film) and sealing the film about the fill material, wherein the capsules comprises a compositions comprising (a) 8-50% by weight of water-dispersible or water-soluble plasticizer, (b) 0.5 to 12% by weight .kappa.-carrageenan, (c) 0 to 60% dextrans, and (d) 1% to 95% by weight water, with the .kappa.-carrageenan comprising at least 50% by weight of all gums forming or contributing to formation of thermoreversible gels in the composition (see abstract). Additions process information is provided in the Example in column 6, which discloses a .kappa.-carrageenan or a blend of .kappa.-carrageenan and iota-carrageenan/gelling salt/mannan gum/xanthan gum (if these materials are present) is dispersed, e.g., at ambient or at least slightly elevated temperature (higher temperatures, of course, usually being advantageous in the physical dissolution of most materials), in a plasticizer (or mixture of plasticizers). Optional additives (e.g., the maltodextrin, gum arabic and protein) are dissolved in water (preferably at about ambient temperature, but some slight elevation or reduction in temperature may be used) to form an aqueous solution. The aqueous solution is added to the .kappa.-carrageenan/plasticizer mixture to form a working composition. The working composition is heated, preferably with stirring to above 130° F to below the boiling point of the working mixture. The heated working composition can then be transferred or introduced for processing to a conventional gelatin encapsulation machine (films are formed by casting the solution on cooled rotating (e.g., metal such as steel) drums, the films are fed through a series of rollers to counter-rotating dies which form, cut and fill capsules of various sizes.

The process for preparing the delivery system of the instant claims differs from the preparation of the delivery system (capsule) of the Gennadios patent by claiming that the gel film thereof comprises .kappa.-2 carrageenan as opposed to .kappa.-carrageenan used in the Gennadios patent.

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However, the substitution of .kappa.-carrageenan with kappa-2 carrageenan is obvious since both compounds are classified as kappa-carrageenan and minor differences in the stability of gel strength between kappa-2 carrageenan and a similar amount of kappa-carrageenan/iota-carrageenan combination does not show unexpected results. Where the claimed and prior art compounds possess a close structural relationship and a specific significant property in common which renders the claimed compounds obvious to one skilled in the art, they are effectively placed in the public domain and unpatentable per se, even though the Applicant has discovered that they possess an additional activity. In re Mod et al. (CCPA 1969) 408 F2d 1055, 161 USPQ 281 ; Monsanto Co. v. Rohm & Haas Co. (DC Pen 1970) 420 Fsupp 950, 164 USPQ 556 (affd. On other grounds, 172 USPQ 323).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to replace the kappa-carrageenan in the delivery system of the Gennadios patent with kappa-2 carrageenan in view of their closely related structures and the resulting expectation of similar film and gelling properties.

Summary

7. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reached on (571) 272-0627. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



E. White



Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600

Continuation of Attachment(s) 6). Other: Information Disclosure Statements (PTO-1449) Considered: Nov. 8, 2004, Aug. 15, 2005, Nov. 14, 2005 & Jan. 9, 2006.